

Message

From: Yan, James [/O=EXCHANGELABS/OU=EXCHANGE ADMINISTRATIVE GROUP (FYDIBOHF23SPDLT)/CN=RECIPIENTS/CN=4E2C11D82EEF4451BA0F6F6B0FCE82B7-YAN, JAMES]
Sent: 2/14/2020 5:46:56 PM
To: Pete Schlom [PSchlom@redstonegrp.com]
Subject: RE: P-20-0025
Attachments: P200025.en1 Sanitized JY DS 02-14-20.pdf

Here is the engineering report.

James Jie Yan, Ph.D.

Chemist/Presidential Management Fellow
New Chemicals Management Branch
Chemical Control Division
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
WJCE-4419D, Mail Code: 7405M
Phone: 202-564-2138
Fax: 202-564-9490
Do not send CBI to this email

From: Pete Schlom <PSchlom@redstonegrp.com>
Sent: Friday, February 14, 2020 10:45 AM
To: Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-0025

Hello James,

Has there been any response regarding the issue below?
Would it be possible to get the engineering RA report?

Regards,

Pete Schlom
Sr. Consultant

110 Polaris Parkway Suite 200
Westerville, Ohio 43082
(614) 923 7472 office
(614) 763-5030 direct
pschlom@redstonegrp.com
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REDSTONE
A Honeywell Company

From: Yan, James <Yan.James@epa.gov>
Sent: Wednesday, February 12, 2020 12:55 PM
To: Pete Schlom <PSchlom@redstonegrp.com>
Subject: RE: P-20-0025

Okay, I will check with RAD about this issue.

-James Yan

From: Pete Schlom <PSchlom@redstonegrp.com>
Sent: Wednesday, February 12, 2020 10:41 AM
To: Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-0025

Hello James,

We are formulating questions and will submit the meeting request as soon as we can.
Can you please provide us with a literature citation that would show the impact of vehicles on degradation of test substances, specifically the inhibition of ester hydrolysis by Arachis (peanut) oil (or other vegetable-based oils) as presented in the review? This request refers to the specific comments made in the discussion of the OECD 422 study summary on p. 8 (of 19). We are aware of the fact that the choice of vehicle can impact biological outcome, but have not seen anything that suggests that hydrolysis of esters in the acidic milieu of the gut is impacted by presence of an ester vehicle. We believe it best for all concerned that we review the same source documents so as to guide our questions to submit. We will then submit our request for a conference along with the questions. Thank you for your collegiality in this matter.

Regards,

Pete Schlom
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REDSTONE
A Safety & Environmental Company

From: Yan, James <Yan.James@epa.gov>
Sent: Tuesday, February 11, 2020 4:31 PM
To: Pete Schlom <PSchlom@redstonegrp.com>
Subject: RE: P-20-0025

Okay. Here is the health report. Unfortunately, RAD cannot arrange any meeting dates before they have the agenda and questions to review. They want to ensure that they have enough time to adequately address any of the issues. Once you have everything figured out on your end, I can put in the meeting request.

James Jie Yan, Ph.D.

Chemist/Presidential Management Fellow
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From: Pete Schlom <PSchlom@redstonegrp.com>
Sent: Tuesday, February 11, 2020 4:17 PM
To: Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-0025

Email is fine – we can't confirm what questions we might have without this report.

Would it be possible to arrange a date for the meeting before we revise our questions and resubmit the request?

Regards,

Pete Schlom
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REDSTONE
A Society & Consultants Company

From: Yan, James <Yan.James@epa.gov>
Sent: Tuesday, February 11, 2020 3:52 PM
To: Pete Schlom <PSchlom@redstonegrp.com>
Subject: RE: P-20-0025

Hello. I could send you the report by mail, and I could email you the report if all CBI is fully redacted. Based on the CBI claims in the submission, there probably would not need to be much further redaction of the report if I emailed it. Do you have a preference?

I canceled the original meeting request and I do not think a time had been set for that. I can request another meeting or reset the original request, although I assume you might have different questions than what you submitted after seeing the final health report and based on the fact that consumer risk is no longer an issue. What would you like to do? I do not know when RAD would be ready for a meeting.

James Jie Yan, Ph.D.

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From: Pete Schlom <PSchlom@redstonegrp.com>
Sent: Tuesday, February 11, 2020 3:35 PM
To: Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-0025

Hello James,

I spoke with our office and there is no functioning FAX machine there. Is it possible to send the information by email? Also, can you confirm our meeting is still on, or will I have to request another one? If it is still on, have you got a date(s) in mind? I assume it will be next week if we do not have to repeat the process.

Regards,

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REDSTONE
A Strong. Connected. Group.

From: Yan, James <Yan.James@epa.gov>
Sent: Thursday, January 30, 2020 9:17 AM
To: Pete Schlom <PSchlom@redstonegrp.com>
Subject: RE: P-20-0025

Looking through our SOPs, we will actually need you to submit a meeting agenda, issue statement, and your questions through CDX in order to set up the discussion. RAD also wants at least two weeks to prepare for the meeting, so I am not sure if we will be able to discuss during February 11-13. Please let me know when you have submitted through CDX so I can put the discussion request in as soon as possible. I apologize for the inconvenience.

-James Yan

From: Yan, James
Sent: Thursday, January 30, 2020 8:57 AM
To: Pete Schlom <PSchlom@redstonegrp.com>
Subject: RE: P-20-0025

Hello. I will check with the availability of the health assessor to discuss this with you. In the mean time, I can try to answer a few of your questions.

- 1) I made a mistake, the metabolite is 2-ethylhexanoic acid, not the alcohol. I am not sure about the assumptions the model uses.
- 2) I believe it is BT4 that is penetrating, not the metabolite.
- 3) BT4 is rated as having poor absorption, which is 15% permeability. I believe the risk calculation assumes 100% is converted to metabolite.
- 4) It is equal to four short duration exposures. The risk calculation is based off an acute exposure over one day.
- 5 and 6) These are best handled by the health assessor.

I will pass along your questions and let you know when I hear back from the health assessor.

James Yan, PhD

Chemist/Presidential Management Fellow

New Chemicals Management Branch

Chemical Control Division

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From: Pete Schlom <PSchlom@redstonegrp.com>

Sent: Thursday, January 30, 2020 8:07 AM

To: Yan, James <Yan.James@epa.gov>

Subject: RE: P-20-0025

Hello James,

Thanks for contacting us regarding the draft health risk assessment. We had an internal meeting with our toxicologist and have some questions for you, which we hope will further clarify the situation for us.

- 1) In my conversation with you, you said modeling indicated BT4 would release 2-ethylhexanol after dermal penetration, which would lead to toxic effects and would require limitation in consumer use by adjusting the formulation. Can you define what assumptions the model uses to reach this conclusion?
- 2) For the model where there is dermal penetration, is it BT4 that penetrates or the metabolite(s)?
- 3) What percent permeability is used in the model and does the model assume 100% of BT4 is converted to metabolites?
- 4) The consumer model used 4 days per year of exposure in modeling oil change activities. Is the four days equal to four short duration exposures or is it actually 96 hours?
- 5) Is there a test we can run to give more confidence in the model predictions?
- 6) Is OECD 428 suitable for addressing the issue created by the model result?

Could we set up a discussion with you regarding the health issues you described? Due to travel by some of our colleagues, the earliest we would be able to meet is the morning of 11 Feb. through morning of 13 Feb.

Regards,

Pete Schlom
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REDSTONE
A Stanley Consultants Company

From: Pete Schlom
Sent: Tuesday, January 28, 2020 2:46 PM
To: Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-0025

Thanks, James.

Regards,

Pete Schlom
Sr. Consultant

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REDSTONE
A Trade Technology Company

From: Yan, James <Yan.James@epa.gov>
Sent: Tuesday, January 28, 2020 2:42 PM
To: Pete Schlom <PSchlom@redstonegrp.com>
Subject: RE: P-20-0025

The engineering and exposure reports have been updated, and they are working on the updated human health risk assessment. I think things are generally on pace at this point. I do not need anything from you right now. I have not yet seen the finalized health report, so I am not sure if there are any issues you need to address, but I will let you know if anything pops up.

-James Yan

From: Pete Schlom <PSchlom@redstonegrp.com>
Sent: Tuesday, January 28, 2020 12:31 PM
To: Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-0025

Hello James,

Thank you for your reply. We appreciate the information you provided and the time to manage it. Can you give me an update of where the review has gotten to at this point?
Do you need any additional commentary from us regarding any of the submission or see any issues that have come up?

Regards,

Pete Schlom
Sr. Consultant

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From: Yan, James <Yan.James@epa.gov>
Sent: Tuesday, January 7, 2020 3:52 PM
To: Pete Schlom <PSchlom@redstonegrp.com>
Subject: RE: P-20-0025

We had already completed the engineering and exposure parts of the review based on the incomplete information provided in the original submission. Now that we have the updated information, we can go back through the process again. I unfortunately do not know how long that will take, but I would expect it to be close to the day 90, especially given the delay to wait for the new information.

James Yan, PhD

Chemist/Presidential Management Fellow

New Chemicals Management Branch

Chemical Control Division

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From: Pete Schlom <PSchlom@redstonegrp.com>
Sent: Tuesday, January 7, 2020 3:00 PM
To: Yan, James <Yan.James@epa.gov>
Subject: RE: P-20-0025

Hi James,

Our client was curious to know where the process is with respect to the various evaluations, etc. Can you comment on when the committee review could happen with this one?

Regards,

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REDSTONE
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From: Yan, James <Yan.James@epa.gov>
Sent: Tuesday, January 7, 2020 1:57 PM

To: Pete Schlom <PSchlom@redstonegrp.com>

Subject: RE: P-20-0025

Hello. I see it. We will review the new information. Thank you.

James Yan, PhD

Chemist/Presidential Management Fellow

New Chemicals Management Branch

Chemical Control Division

Office of Pollution Prevention and Toxics

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From: Pete Schlom <PSchlom@redstonegrp.com>

Sent: Tuesday, January 7, 2020 1:26 PM

To: Yan, James <Yan.James@epa.gov>

Subject: P-20-0025

Hello James,

This amended PMN has been submitted.

Regards,

Pete Schlom

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